

# Judge Rebuffs FDA on Effort to Ban Diet Supplement

Submit written comments to:

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Dockets Management Branch (HFA-305) FDA  
200 C. St. SW  
Washington, DC 20204

Re: [Docket No. 98 N-044] RIN 0910-AA59 Regulations on Statements  
Made for Dietary Supplements Concerning the Effect of the Product on the  
Structure or Function of the Body

To whom it may concern at FDA:

Your proposed rule will have an adverse effect on public health by placing arbitrary and capricious limits on the allowable health information to be presented to consumers at the point of sale on dietary supplements, in complete violation of the first amendment. Your definition of disease is overly broad. You are clearly over reaching here. Under proposed § 101.93(g)(1) a disease is any deviation from, impairment of, or interruption of the normal structure or function of any part, organ, or system (or combination thereof) of the body that is manifested by a characteristic set of one or more signs or symptoms.)

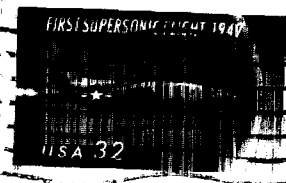
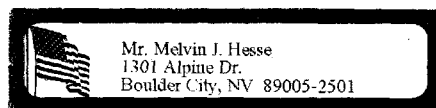
Thus, in your zeal to "insure that dietary supplements don't act as a disincentive to new drug development" (the "immortal" words of Gary Dykstra), you would even disallow structure/function claims relative to aging: ie, "hot flashes". (Since when are "aging" or the menopause "disease states"?)

Judge Dale Kimball just issued an injunction against you forcing you to lift your ban on cholestin, which he declared was a dietary supplement under the terms of DSHEA. You tried to ban this safe Chinese red rice yeast extract which helps lower cholesterol, because its sale angers Merck. We remind you that dietary supplements were specifically exempted from the harmonization language in the FDA Reform Bill, and that Congress was flooded with faxes, email and outraged calls on this issue as recently as October, 1997. Prior to that, in 1994 Congress received more mail on this issue than on anything since the Vietnam war. For the sake of the public health, we strongly urge you to stop blurring the distinction between a disease, and a health condition. Stop trying to harmonize our laws to EEC 65/65 in the EU, where dietary supplements are regulated as "drugs."

Signed: Melvin R. Hesse  
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(Info provided by International Advocates for Health Freedom)

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